TALO-S TABLETS

Escitalopram 10 mg

COMPOSITION

Each tablet contains Escitalopram Oxalate equivalent to Escitalopram 10 mg. Excipients: q.s. as per approved formulation.

DESCRIPTION AND PHARMACOLOGY

Escitalopram is a selective serotonin reuptake inhibitor (SSRI) antidepressant. It inhibits neuronal reuptake of serotonin (5-HT), increasing serotonergic activity in the central nervous system. Escitalopram is the S-enantiomer of citalopram.

PHARMACOKINETICS

Following oral administration, escitalopram is well absorbed; peak plasma concentrations occur in approximately 5 hours. Food does not materially affect absorption. Plasma protein binding is approximately 56%. It is metabolized mainly in the liver and has an elimination half-life of about 27-32 hours. Steady state is usually reached within approximately one week.

THERAPEUTIC INDICATIONS

Treatment of major depressive disorder in adults and adolescents aged 12 years and above, and generalized anxiety disorder in adults, subject to locally approved indications. Use only on medical prescription.

DOSAGE AND ADMINISTRATION

Adults with depression or generalized anxiety disorder: usual starting and recommended dose is 10 mg orally once daily. If clinically indicated and tolerated, the prescriber may increase to a maximum of 20 mg daily after at least one week. Adolescents aged 12-17 years with depression: 10 mg once daily; any increase should occur after at least three weeks under specialist supervision. Take in the morning or evening, with or without food. Do not exceed prescribed dose.

SPECIAL POPULATIONS

Elderly patients and patients with hepatic impairment: generally 10 mg once daily. Mild or moderate renal impairment: generally no adjustment; use caution in severe renal impairment. Safety and effectiveness in other pediatric populations depend on the locally approved label.

CONTRAINDICATIONS

Hypersensitivity to escitalopram, citalopram, or formulation components. Concurrent use with monoamine oxidase inhibitors (MAOIs), including linezolid or intravenous methylene blue; observe a minimum 14-day interval between escitalopram and an MAOI used for psychiatric disorders. Concurrent pimozide use is contraindicated.

IMPORTANT WARNING: SUICIDAL THOUGHTS AND BEHAVIOURS

Antidepressants increase the risk of suicidal thoughts and behaviour in children, adolescents and young adults, particularly during early treatment or dose changes. Monitor all patients closely for worsening depression, agitation, unusual behavioural changes or suicidality. Families and caregivers should seek immediate medical assistance if these occur.

WARNINGS AND PRECAUTIONS

Serotonin syndrome may be life-threatening, particularly with other serotonergic drugs; symptoms include agitation, fever, sweating, tremor, muscle rigidity and diarrhoea. Discontinue and seek urgent care if suspected. Screen for bipolar disorder before use; mania/hypomania may occur. Caution in patients with seizures, bleeding disorders, hyponatraemia risk, angle-closure glaucoma, cardiac disease or QT-prolongation risk. Escitalopram may impair alertness; use caution when driving or operating machinery.

DISCONTINUATION

Do not stop abruptly. Taper gradually under medical supervision to reduce withdrawal symptoms such as dizziness, sensory disturbances, insomnia, anxiety, nausea and headache. If significant symptoms occur, the prescriber may adjust the taper.

DRUG INTERACTIONS

Avoid MAOIs, pimozide and other contraindicated combinations. Other SSRIs/SNRIs, triptans, tramadol, fentanyl, lithium, buspirone, amphetamines and St John's wort may increase serotonin syndrome risk. NSAIDs, aspirin, anticoagulants and antiplatelet agents increase bleeding risk. Cimetidine and some CYP2C19 inhibitors may increase escitalopram exposure. Alcohol is not recommended. Review all prescription, over-the-counter and herbal medicines.

PREGNANCY AND LACTATION

Use in pregnancy only after individual assessment of maternal benefit and fetal risk. Late-pregnancy exposure to SSRIs may be associated with neonatal adaptation complications and persistent pulmonary hypertension of the newborn. Escitalopram passes into breast milk; monitor breastfed infants for sedation, poor feeding or inadequate weight gain. Do not discontinue treatment without medical advice.

UNDESIRABLE EFFECTS

Common: nausea, insomnia or somnolence, headache, dizziness, sweating, fatigue, dry mouth, constipation, diarrhoea and sexual dysfunction. Serious reactions include suicidal behaviour, serotonin syndrome, abnormal bleeding, severe hyponatraemia, seizures, mania, severe allergic reactions and cardiac rhythm disturbances. Seek medical help for serious or persistent effects.

OVERDOSAGE

Symptoms may include dizziness, tremor, agitation, nausea, vomiting, tachycardia, seizures, serotonin syndrome and ECG changes. Obtain emergency medical attention. Management is supportive with monitoring of vital signs and cardiac rhythm; there is no specific antidote.

MISSED DOSE

Take a missed dose when remembered unless it is nearly time for the next dose. Skip the missed dose in that case. Do not take two doses together.

STORAGE

Store in accordance with the approved product label, protected from moisture and excessive heat. Keep out of the reach of children.

PRESENTATION

Talo-S Tablets: Escitalopram 10 mg. Pack size: 10 tablets.

MANUFACTURED BY

Vega Pharmaceuticals (Pvt.) Ltd.